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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0186]

Draft Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements." This draft guidance is neither final nor is it in effect at this time. Metallic plasma spray coatings, both porous and nonporous, and metallic sintered or diffusion bonded porous coatings are used to attach artificial joints to living bone. FDA's Center for Devices and Radiological Health (CDRH) is identifying a set of testing methods that will accurately compare the mechanical properties of metallic plasma spray coatings with the same properties of sintered or diffusion bonded porous coatings. This draft guidance document proposes to use a number of mechanical tests to compare the mechanical properties of the various types of coatings. CDRH needs the ability to make the above comparisons in order to identify coated hip devices that should be subject to postmarket surveillance requirements.

DATES: Written comments concerning this draft guidance document must be received by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma

Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements'' to the Division of Small Manufacturers Assistance (HFZ-220), CDRH, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. **FOR FURTHER INFORMATION CONTACT:** Anita M. Rayner, Center for Devices and Radiological Health (HFZ-543), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-0006.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the reclassification and codification of the hip joint, metal/polymer/metal, semi-constrained, porous-coated uncemented prostheses in the **Federal Register** of January 8, 1993 (58 FR 3227). The reclassification was effective February 21, 1992. On February 15, 1994, CDRH's Orthopedic and Rehabilitation Devices Branch determined that hip prostheses using plasma sprayed porous coatings for biological fixation can be substantially equivalent to the reclassified porous coated hip prosthesis. As part of the decision CDRH, using the then existing authority of section 522(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act, required manufacturers of plasma spray porous coated hip prostheses to conduct postmarket surveillance of their devices. Postmarket surveillance was required because of CDRH's concern that reported differences between the mechanical properties, particularly abrasion resistance, of plasma sprayed coatings and sintered and diffusion bonded porous coatings could have an adverse effect on the long-term revision rate of the plasma sprayed devices. While CDRH has clinical data describing the long-term revision rate of sintered and diffusion bonded porous coated hip prostheses, CDRH does not have this

type of data on the cementless use of plasma sprayed hip prostheses. The postmarket surveillance will consist of prospective, long-term, followup of a population of patients who have received a cementless implantation of the manufacturer's plasma sprayed porous coated hip prosthesis. The objective of the patient followup is to determine the long-term revision rate for each plasma sprayed porous coated hip prosthesis.

At the time postmarket surveillance was required, CDRH believed that the term "plasma spray" was a single manufacturing technique that produced a single form of coating with a single set of metallurgical and mechanical properties. CDRH now recognizes that plasma spray manufacturing methods are a subset of the larger, thermal spray group of metallic coating production methods. CDRH has come to recognize that thermal spray coating methods can produce coatings with a wide range of metallurgical and mechanical properties. As an example, CDRH originally believed that, when used to apply metallic coatings to hip prostheses, plasma spray manufacturing techniques were used to produce only porous coatings. CDRH now also recognizes that hip prostheses with nonporous metallic coatings are also manufactured by plasma spray and other thermal spray methods.

Several manufacturers, using a variety of thermal spray coating methods, have received substantial equivalence decisions for their coated hips. A number of these manufacturers have sought reconsideration of CDRH's decision to require postmarket surveillance of their products. Several of the requests for reconsideration are, in part, based on claims that manufacturing technology permits the production of plasma sprayed coatings with mechanical properties, particularly abrasion resistance, equal to or better than those of the sintered or diffusion bonded porous coatings upon which the reclassification was based. In response to the requests for reconsideration, CDRH released a draft guidance document describing testing methods that CDRH believed could compare the mechanical properties of plasma sprayed coatings with those of sintered and diffusion bonded porous coatings. Several comments on that draft guidance document were received. Some comments on that draft guidance document included mechanical test data on

different thermal spray coatings, both porous and nonporous. These data indicate that thermal spray coatings can have mechanical properties greater than, less than, or almost equal to those of sintered or diffusion bonded porous coatings.

CDRH does not believe that postmarket surveillance is necessary for hip prostheses whose coatings have mechanical properties, particularly abrasion resistance, equal to or better than sintered or diffusion bonded porous coatings. As a result, CDRH is now proposing to use the mechanical test methods described in this draft guidance document to reevaluate, on a case-by-case basis, the need for manufacturers to conduct postmarket surveillance of their metallic thermal spray coated hip prostheses.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on what data are necessary to support reconsideration of the thermal spray coated hip prosthesis postmarket surveillance requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

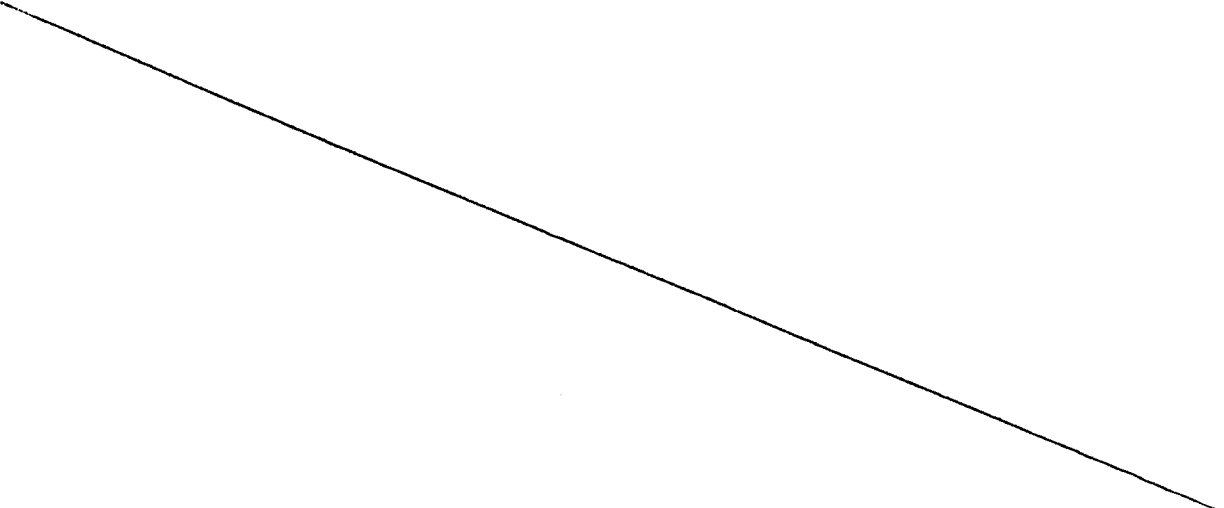
In order to receive "Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts,

at second voice prompt press 2, and then enter the document number 946 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes “Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements,” device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at “<http://www.fda.gov/cdrh>”. “Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements” will be available at “<http://www.fda.gov/cdrh/postsurv>”.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found



in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/8/99
February 8, 1999

Linda S. Kahan

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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